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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with regulatory provisions, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC). This is a hybrid meeting, accessible both in person and virtually. It is open to the public, limited only by the in-person space available. The public is also welcome to view the meeting by joining the audio conference (information below). Time will be available for public comment, and the public is also welcome to submit written comments in advance of the meeting (see the public participation section below).

DATES: The meeting will be held on November 8, 2023, from 8:30 a.m. to 5:30 p.m., EST, and November 9, 2023, from 8:30 a.m. to 12 p.m., EST.

ADDRESSES: Centers for Disease Control and Prevention, 2400 Century Parkway, NE, Room 1020/1023, Atlanta, Georgia 30345. The conference room will have seating for approximately 60 people.

Meeting Information: All people attending the CLIAC meeting in person are required to register online for the meeting at least five business days in advance for U.S. citizens and at least 20 business days in advance for international registrants. Register at: https://www.cdc.gov/cliac/upcoming-meeting.html. Register by scrolling down and clicking the "Register for this Meeting" button and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than November 1, 2023, for U.S. registrants and October 11, 2023, for international registrants.

The confirmed meeting times, agenda items, and meeting materials, including instructions for accessing the live meeting broadcast, will be available on the CLIAC website at https://www.cdc.gov/cliac/upcoming-meeting.html.

FOR FURTHER INFORMATION CONTACT: Heather Stang, MS, Senior Advisor for Clinical Laboratories, Division of Laboratory Systems**,** Office of Laboratory Science and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop V24-3, Atlanta, Georgia 30329-4027. Telephone: (404) 498-2769; Email: HStang@cdc.gov.

SUPPLEMENTARY INFORMATION:

PURPOSE: The Clinical Laboratory Improvement Advisory Committee (CLIAC) is charged with providing scientific and technical advice and guidance to the Secretary, Department of Health and Human Services; the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention (CDC); the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare & Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine and specific questions related to possible revision of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards. Examples include providing guidance on studies designed to improve quality, safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

MATTERS TO BE CONSIDERED: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and CLIAC discussions will focus on the final report from the CLIA Regulations Assessment Workgroup, efforts to address the CLIA top 10 laboratory deficiencies,

standardization of test result communication, and the role of the laboratory in antibiotic stewardship. Agenda items are subject to change as priorities dictate.

Public Participation

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments pertinent to agenda items.

Oral Public Comment: Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item. In general, each individual or group requesting to present an oral comment will be limited to a total time of five minutes (unless otherwise indicated). Speakers should email CLIAC@cdc.gov or notify the contact person above (see FOR FURTHER INFORMATION CONTACT) at least five business days prior to the meeting date.

Written Public Comment: CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least five business days prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments should be submitted by email to CLIAC@cdc.gov or to the contact person above. All written comments will be included in the meeting minutes posted on the CLIAC website.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign *Federal Register* notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives,

Office of the Chief Operating Officer,

Centers for Disease Control and Prevention.

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